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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/571,992

02/07/2007

Nina Rautonen

14923.0032

5592

27890 7590 11/26/2010
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EXAMINER

MACAULEY, SHERIDAN R

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

11/26/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	<p>Application No. 10/571,992</p>	<p>Applicant(s) RAUTONEN ET AL.</p>	
	<p>Examiner SHERIDAN R. MACAULEY</p>	<p>Art Unit 1651</p>	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 01 November 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 22-24 and 28.
Claim(s) withdrawn from consideration: 1-21 and 29-39.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____.
13. ☒ Other: See Continuation Sheet.

/Ruth A. Davis/
Primary Examiner, Art Unit 1651

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's arguments have been considered, but they have not been found to be persuasive. Applicant argues that the cited references do not render obvious the claimed invention. Specifically, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant case, although applicant argues that no motivation existed in the art for one to use the strain of bacteria recited in the claims in the claimed method, the strain recited in the claims (*Bifidobacterium* sp. 420) was known in the art at the time of the invention, as taught by Van Der Mei. The reference further teaches that the species may have probiotic effects. One of ordinary skill in the art would have been motivated to use *Bifidobacterium* sp. 420 in the method of Collins because Collins teaches that any species of *Bifidobacterium* with probiotic effects may be used in the method, and further teaches methods for testing such strains for probiotic effects. One would therefore have recognized that *Bifidobacterium* sp. 420 could have been tested for such effects and used in the methods of Collins. Therefore, the instant claims are rendered obvious by the prior art, as discussed in detail in the rejections above. Although applicant further argues that the strain provides a specific advantage over the strain used by Collins, in that the strain used in the instantly claimed method has direct effects on epithelial COX gene expression, it is noted that the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new. Thus the claiming of a new use, functions or unknown property that is inherently present in the prior art does not necessarily make the claim patentable (MPEP 2112). In the instant case, the bacterial strain (*Bifidobacterium* sp. 420) was known in the prior art, and the composition was known to be useful as a probiotic. Thus, the explanation of the mechanisms by which the probiotic composition is effective does not render the claim patentable. Furthermore, even if the results cited by applicant were found to provide a benefit over the compositions of the prior art, applicant's evidence of surprising results is not commensurate with the scope of the claims. Applicant asserts that the *Bifidobacterium* sp. 420 composition has direct effects on epithelial COX gene expression; however, the claims are directed to any increase in the amount of COX-1 mRNA in any cell of the subject. Therefore, applicant's arguments regarding the unexpected advantages of the claimed method are not found to be persuasive. Further, although applicant argues that the cited prior art does not teach the limitations of claim 28, specifically that the prior art does not teach the use of a betaine replacement, it is noted that the combined prior art renders obvious the use of choline (a betaine replacement) in the claimed method, as discussed in the previous Office action at pp. 6-7, par. 14-18. Therefore, applicant's arguments have been considered, but they have not been found to be persuasive.

Continuation of 13. Other: The amendments to the specification are entered and overcome the objections to the specification made in the previous Office action. No claim amendments were included in the reply filed on 01 November 2010.